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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,705	12/02/2004	Takahito Hara	3056 USOP	1003
21874 7590 04/22/2008 EDWARDS ANGELL PALMER & DODGE LLP P.O. BOX 55874 BOSTON, MA 02205				
EXAMINER				
BRISTOL, LYNN ANNE				
ART UNIT		PAPER NUMBER		
1643				
MAIL DATE		DELIVERY MODE		
04/22/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

10/516,705

Applicant(s)

HARA ET AL.

Examiner

LYNN BRISTOL

Art Unit

1643

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 25 March 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: 12 and 71-76.
Claim(s) withdrawn from consideration: 1-11 and 13-64.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____.
13. ☐ Other: _____.

/Larry R. Helms/
Supervisory Patent Examiner, Art Unit 1643

Continuation of 5. Applicant's reply has overcome the following rejection(s): rejection of Claims 73 and 75 under 112, 2nd paragraph [IF, IF ENTERED].

Continuation of 11. does NOT place the application in condition for allowance because:

The rejection of Claims 12, 71 and 72 under 112, 1st paragraph for lack of written support for the limitation "for at least three months" is maintained. The specification teaches the culture period can last for "at latest or by no later than 3 months or so" (p. 69, lines 11-14); and Example 1 where "cultivation was continued for 6 weeks to 13 weeks or more." Applicants allegation in the Response of 3/25/08 is that on p. 69 at lines 14-16 of the specification, additional support can be found for the range. The examiner submits that the recited passage qualifies that for some compounds, it is expected that no proliferation would be observed within "at latest in about 3 months or so", even when cultivation is continued for a longer period. Thus it is maintained that there is no per se indication set forth in the specification that the culture period is "at least 3 months" which includes 13 weeks but an infinitely upper limit. Finally, Applicants admission of record on p. 14 of the Response that "culturing of cells for 13 weeks provides support for the term "at least three months"" wholly ignores the issue of the infinite range limit. How specific and selective is culturing the cells in the presence of any compound for an infinite period of time? If non-specific effects of long-term culturing could effect the cells, would this also raise other issues regarding enablement?

The rejection of Claims 73 (and now Claims 74-76) under 112, 1st paragraph for lack of enablement in requiring a biological deposit is maintained. Applicants allege that any one of skill in the art could produce any cancer cell with the exact, claimed amino acid substitutions in the protein of SEQ ID NO:2 by following the specification on p. 67, lines 7-15 and p. 74, lines 3-4, and based on the copies of two reference articles describing making mutated genes in cells and living animals; and in Example 1 of the specification using the LNCaP-FGC cell line (ATCC No. CRL-1740) as starting material. The examiner submits that the claimed method is drawn to any cancer cell comprising the amino acid substituted human androgen receptor of SEQ ID NO:2. Claims 73-75 are not limited to any kind of cancer cell and Claim 76 is drawn to any prostate cancer cell. Applicants have shown that only the human prostate carcinoma cell line LNCaP-FGC could be cultured under the conditions set forth in Example 1 to produce cell lines with amino acid substitutions of leucine or cysteine for tryptophan at position 746 and alanine for threonine at position 882, namely, cell lines LNCaP-cx11 and LNCaP-cx2, respectively. Applicants have not shown the reproducibility and predictability of generating a cell line(s) with these precise amino acid substitutions under the exact culture conditions.